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Assistant Commissioner for Patents, Washington, D.C. 20231.

Date of Signature and Deposit: February 2, 1998

PATENT #11

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: James A. Thomson

Date: February 2, 1998

Serial No.: 08/591,246

Group Art Unit: 1815

Filed: January 18, 1996

Examiner: B. Brumback

For: PRIMATE EMBRYONIC STEM CELLS File No.: 960296.93723

RESPONSE

Assistant Commissioner For Patents
Washington DC 20231

Dear Sir:

In response to the Office Action dated December 28, 1997 in the file of the above-identified application, the applicant responds with the following remarks and the Declaration submitted herewith:

In the Office Action dated December 18, 1997 in the file of this application, the rejection of Claims 1 to 11 under 35 U.S.C. § 112, first paragraph, for the deposit requirement was maintained. This was the only rejection applied by the Examiner against the claims of the application. The Examiner also indicated, in paragraph 11, that the amendment to the claims to recite the limitation to a specific cell line designated as R278.5, and compliance with the deposit requirement, would place the claims in condition for allowance.

The applicant submits herewith that the Examiner's requirement that a deposit be made in conjunction with the filing of this application is inappropriate. For similar and related reasons, the applicant asserts that the claims of this application should not be limited to the exemplary cell line R278.5.

The applicant first wishes to thank the Examiners Brumback and Woodward for the telephone interview granted on

January 22, 1998 with the undersigned. During that interview, arguments related to the deposit requirement and the scope of the claims. Those argument are recapitulated in this response. Also in the interview, the applicant indicated a willingness to supply a Declaration Under 37 C.F.R. §1.132, containing additional information about the testing which had been conducted on the primate embryonic stem cells created in the applicant's laboratory. Such a Declaration is submitted herewith.

In the Declaration, inventor Dr. James Thomson provides additional information about the numerous other cell lines created through the procedures described in this patent application. Dr. Thomson believes, based on experimental and research evidence so far, that it is readily possible to recreate any number of independent primate embryonic stem cell lines using the methods described in the present patent application. While his laboratory has not tested every cell line so far created for every one of the criteria described in the application, all the criteria have been applied to some of the cell lines no negative results have been obtained from the cell lines identified. These cell lines also have a distinctive morphology which is reproducible, recognizable and distinguishable. In short, it is readily possible to make any number of cell lines using the methods of the present invention which cell lines meet the limitations contained in the claims of the present application.

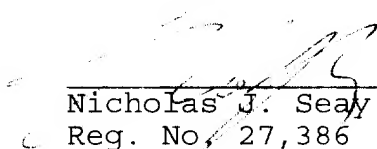
As regard the deposit requirement imposed by the Examiner, please note that no claim in this application claims any specific cell line. This is not an accident. The applicant does not believe that any particular one of the embryonic cell lines created by the applicant is particularly more valuable than any other. What the applicant has done here is describe a methodology which can be used to create any number of cell lines having defined characteristics. Accordingly, since the methods described for creating those cell lines are carefully described in the specification, and since the specification may be followed to create any desired

number of such cell lines, it is the applicant's understanding that a deposit should not be required, since the application itself is fully enabling for the invention described.

Similarly, the applicant believes that the claims of the present invention cover subject matter beyond the exemplified cell line R278.5. The applicant's disclosure defines a methodology to create any number of other cell lines having similar useful characteristics. It is for that reason, that the claims describe primate embryonic cell lines by those characteristics, which characteristics define the cell lines created to be unique and distinct from those which had previously existed in the art. The cell lines created through the methodology of the present specification have been explicitly described in the claims by those characteristics which make them unique. Accordingly, it is believed that the claims ought to be broader than the one exemplified cell line R278.5, and should encompass the other cell lines created by the methodologies described in the application.

For that reason, it is requested that the Examiner reconsider the merits of this rejection. It is believed by the applicant that no deposit is necessary to enable this application and further that the claims as they are presently pending are properly commensurate with the scope of what has been enabled by this application.

Respectfully submitted,



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U.S. Department of Commerce
 Patent and Trademark Office

FEE TRANSMITTAL

FEB 12 1998

Complete if Known

Application Number	08/591,246
Filing Date	01/18/96
First Named Inventor	James A. Thomson
Group Art Unit	1815
Examiner Name	B. Brumback
Attorney Docket Number	920296.93723

TOTAL AMOUNT OF PAYMENT

\$

METHOD OF PAYMENT (check one)

1. ☒ The Commissioner is hereby authorized to charge indicated fees and credit any over payments to:

Deposit Account Number 17-0055

Deposit Account Name Quarles & Brady

- ☒ Charge Any Additional Fee Required Under 37 CFR 1.16 and 1.17 ☐ Charge the Issue Fee Set in 37 CFR 1.18 at the Mailing of the Notice of Allowance, 37 CFR 1.311(b)

2. ☐ Payment Enclosed:

☐ Check ☐ Money Order ☐ Other

FEE CALCULATION (fees effective 10/01/97)

1. FILING FEE

Large Fee Code	Entity Fee (\$)	Small Fee Code	Entity Fee (\$)	Fee Description	Fee Paid
101	790	201	395	Utility filing fee	
106	330	206	165	Design filing fee	
107	540	207	270	Plant filing fee	
108	790	208	395	Reissue filing fee	
114	150	214	75	Provisional filing fee	

SUBTOTAL (1) (\$)

2. CLAIMS

Total Claims	Extra	Fee from below	Fee Paid
-20=	X		
Independent Claims	-3=	X	
Multiple Dependent Claims			

Large Fee Code	Entity Fee (\$)	Small Fee Code	Entity Fee (\$)	Fee Description
103	22	203	11	Claims in excess of 20
102	82	202	41	Independent claims in excess of 3
104	270	204	135	Multiple dependent claim
109	82	209	41	Reissue independent claims over original patent
110	22	210	11	Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$)

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Fee Code	Entity Fee (\$)	Small Fee Code	Entity Fee (\$)	Fee Description	Fee Paid
105	130	205	65	Surcharge - late filing fee or oath	
127	50	227	25	Surcharge - late provisional filing fee or cover sheet	
139	130	139	130	Non-English specification	
147	2,520	147	2,520	For filing a request for reexamination	
112	920	112	920	Requesting publication of SIR prior to Examiner action	
113	1,840	113	1,840	Requesting publication of SIR after Examiner action	
115	110	215	55	Extension for response within first month	
116	400	216	200	Extension for response within second month	
117	950	217	475	Extension for response within third month	
118	1,510	218	755	Extension for response within fourth month	
119	310	219	155	Notice of Appeal	
120	310	220	155	Filing a brief in support of an appeal	
121	270	221	135	Request for oral hearing	
138	1,510	138	1,510	Petition to institute a public use proceeding	
140	110	240	55	Petition to revive unavocably abandoned application	
141	1,320	241	660	Petition to revive unintentionally abandoned application	
142	1,320	242	660	Utility issue fee (or reissue)	
143	450	243	225	Design issue fee	
144	670	244	335	Plant issue fee	
122	130	122	130	Petitions to the Commissioner	
123	50	123	50	Petitions related to provisional applications	
126	240	126	240	Submission of Information Disclosure Stmt	
581	40	581	40	Recording each patent assignment per property (times number of properties)	
146	790	246	395	Filing a submission after final rejection (37 CFR 1.129(a))	
149	790	249	395	For each additional invention to be examined (37 CFR 1.129(b))	

Other fee (specify)

Other fee (specify)

SUBTOTAL (3) (\$)

* Reduced by Basic Filing Fee Paid

SUBMITTED BY

Typed or Printed Name Nicholas J. Seay

Complete (if applicable)

Reg. Number 27,386